DEPARTMENT OF HE/ H & HUMAN SERVICES M1006N Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-66

June 18, 1997

Mr. Gregory Lewis
President, Nova Medical Corporation
3500 N. State Road 7
Ft. Lauderdale, Florida 33319

Dear Mr. Lewis:

This letter is in reference to Skin-Cap® Spray, which contains the active ingredient, zinc pyrithione, and is distributed by your firm. This product is offered for over-the-counter (OTC) sale and promotional labeling for this product designates its use for the treatment of dandruff, seborrheic dermatitis, and psoriasis. Because of these claims, the product is considered a drug as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The product, Skin-Cap® Spray, is adulterated within the meaning of Section 501(c) of the Act in that it is a drug not recognized in an official compendium and its strength differs from, or its quality or purity falls below that which it purports or is represented to possess. Analysis has determined that of two (2) canisters examined, one contained 66% of the amount of zinc pyrithione declared on the label, and the other contains 13% of the declared amount.

Skin-Cap® Spray is subject to final regulations on Drug Products for the Control of Dandruff, Seborrheic Dermatitis and Psoriasis (Title 21, Code of Federal Regulations, Parts 358.701 to 750), which became effective on December 4, 1992. This product fails to meet all the requirements of the final regulations. Since a claim for psoriasis treatment is not permitted for the active ingredient, zinc pyrithione, the product is a new drug under Section 201(p) of the Act. A new drug may not be legally marketed in the United States without an approved New Drug Application as described in Section 505 of the Act. This product is also misbranded since the labeling does not include the complete "statement of identity" and adequate directions for use as stated in Section 502 of the Act. This product is further misbranded because its promotional labeling uses the terms "certified by the FDA" and "approved by the FDA" which is not the case (Section 502).

The violations cited in this letter are not intended to constitute an all-inclusive list of the violations that may exist for products marketed by your firm. A review of all your firm's products for compliance with the requirements of the Act should be conducted. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of government contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct them may result in Food and Drug Administration initiated regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, Attn: Martin E. Katz, Compliance Officer, (407) 648-6823, ext. 262.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District

cc: [redacted]